



Filed on behalf of Watanabe et al.

Paper No. _____

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UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

**FUMIHIKO WATANABE, HIROSHIGE TSUZUKI
AND MITSUAKI OHTANI**

**Junior Party
(U.S. Patent Application 09/120,383),**

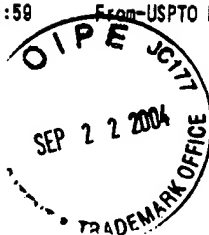
v.

**Patrick Michael O'Brien and Drago Robert Sliskovic
Senior Party,**

(U.S. Patent No. 5,756,545).

Patent Interference No. 105,010 (MPT)

**WATANABE SECOND AMENDMENT AND REMARKS
(to Add Claims 34-36)**



The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper No. 46

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Filed:
February 20, 2003

UNITED STATES PATENT AND TRADEMARK OFFICE

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AND INTERFERENCES

FAXED

FUMIHIKO WATANABE, HIROSHIGE TSUZUKI
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FEB 20 2003

Junior Party
(U.S. Patent Application 09/120,383),

**PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
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v.

PATRICK MICHAEL O'BRIEN AND DRAGO ROBERT SLISKOVIC
Senior Party,
(U.S. Patent No. 5,756,545).

Patent Interference No. 105,010 (MPT)

DECISION ON EXPEDITED PRELIMINARY MOTIONS

A telephone conference call was held on February 19, 2002, at approximately 2:00 p.m.,
involving:

1. Michael P. Tierney, Administrative Patent Judge
2. Dr. Eric Baude, counsel for O'Brien.
3. Stephen Macbius and George Quillin, counsel for Watanabe.

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The principal purpose of the conference call was to discuss Watanabe's expedited motions, which are as follows:

1. Watanabe Revised Preliminary Motion 3, to substitute counts. (Paper No. 36).
2. Watanabe Revised Preliminary Motion 4, to add application claims corresponding to a count. (Paper No. 37).

As discussed during the conference call, Watanabe Revised Preliminary Motions 3 and 4 are granted-in-part. Specifically, Watanabe's request to substitute counts A and C for Counts 1 and 2 is denied, but Watanabe's contingent request to substitute counts D and E for Counts 1 and 2 is granted. Further, Watanabe's request to add new claims 33 and 36 is denied but the request to add new claims 34 and 35 is granted.

A brief summary of the findings of fact and conclusions of law are provided below. A more detailed statement will follow in due course.

Watanabe Revised Preliminary Motion 3

Watanabe requests the substitution of new counts A and C for the present Counts 1 and 2. Further, should that request be denied, Watanabe requests entry of new counts D and E for Counts 1 and 2. (Watanabe Revised Preliminary Motion 3, Paper No. 36). O'Brien opposes. (O'Brien Opposition 1, Paper No. 40).

A count defines the interfering subject matter. 37 C.F.R. §1.601(f). Thus, one consideration in evaluating a proposed count is whether or not the count properly defines the common subject matter, i.e., the potential 35 U.S.C. §102(g) prior art, as between the parties.

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As the count represents the potential 35 U.S.C. §102(g) prior art, a criteria for a proper count is that it represent the "same patentable" invention. See, e.g., 37 C.F.R. §1.601(n).

Watanabe alleges that the proposed counts represent the same patentable invention as that claimed by both parties. (Paper No. 36, p. 17 and Watanabe Revised Preliminary Motion 4, Paper No. 37, p. 11). Specifically, Watanabe argues that the proposed counts are proper as the subject matter encompassed by the proposed counts would render obvious O'Brien's claimed invention. O'Brien disagrees.

Proposed Counts A and C

According to Watanabe proposed counts A and C differ from Counts 1 and 2 in only one aspect, O'Brien's R¹ substituent. (Paper No. 36, pages 12-14). In Counts 1 and 2, R¹ is a C₁-C₆ alkyl or halogen whereas in proposed counts A and C R¹ also includes hydrogen. (Compare O'Brien claim 1 with Watanabe claim 33).

O'Brien, however, contends that proposed counts A and C differ from Counts 1 and 2 in two material ways. O'Brien agrees that the first difference is in the inclusion of hydrogen in the R¹ substituent but also identifies a difference in the R² substituent. According to O'Brien, R² in Counts 1 and 2 is hydrogen or C₁-C₆ alkyl, where the alkyl is optionally substituted by a group such as a phenyl or OR⁶ where the R⁶ can be hydrogen, C₁-C₆ alkyl, C₁-C₆ alkanoyl, phenyl or substituted phenyl. (Paper No. 40, pages 16-19). In contrast, proposed counts A and C require that R² is a benzyloxymethyl group.

Watanabe argues that the term "phenyl" as used in Counts 1 and 2 include benzyl. Count

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1 is O'Brien claim 1 and Count 2 is O'Brien claim 14. According to Watanabe, giving O'Brien claims 1 and 14 their broadest reasonable meaning, the term phenyl should encompass benzyl. For such an interpretation, Watanabe identifies O'Brien involved '545 specification, which states that the "R² alkyl group can be substituted with phenyl, e.g., benzyl, . . ." (WX 2001, col. 2, lines 59-60).

Claims and their terms are to be given their broadest reasonable meaning in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise may be afforded by written description contained in applicant's specification. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). In providing the broadest reasonable meaning for the claim terms there is a heavy presumption in favor of the ordinary meaning of claim language. *Kraft Foods Inc. v. International Trading Co.*, 203 F.3d 1362, 1366, 53 USPQ2d 1814, 1817 (Fed. Cir. 2000). Thus, to construe O'Brien's claim language and the counts that they represent, we begin with the words of the claim. *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331, 59 USPQ2d 1401, 1406-07 (Fed. Cir. 2001).

The ordinary and customary meaning of the term phenyl is the -C₆H₅ radical. (Declaration of Joseph Picard, OX 1002, ¶45). The ordinary meaning of the term benzyl is phenylmethyl. (OX 1002, ¶47). Thus, a benzyl group has a methylene group (-CH₂-) whereas phenyl does not. (OX 1002, ¶49). Thus, the term "phenyl" would not normally encompass a benzyl group.

O'Brien's specification indicates that an example of an R² substituent is an alkyl group

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substituted with phenyl, such as benzyl. (WX 2001, col. 2, lines 59-60). This teaching, however, must be placed in proper context. The specification does not evidence an intent that phenyl itself encompasses benzyl, but rather that an example of an alkyl substituted with phenyl is benzyl. Specifically, a C₁ alkyl, i.e., methyl, that is substituted with phenyl would be benzyl.

Additionally, the APJ notes that Watanabe's claims contain a benzyloxymethyl group. For such a group to correspond to O'Brien's claims, O'Brien R² would have to be a C₁ alkyl substituted with OR⁶ wherein R⁶ is benzyl. Yet, Watanabe has failed to demonstrate that O'Brien expressed an intent to define the R⁶ substituent as encompassing benzyl. Specifically, O'Brien defines R⁶ as encompassing phenyl, however, O'Brien does not appear to indicate that the phenyl of R⁶ can be a benzyl.

O'Brien's specification fails to evidence an express intent to alter the ordinary and customary meaning of the term phenyl. Accordingly, the term phenyl as used in O'Brien claims 1 and 14, and thus Counts 1 and 2, is interpreted to mean a -C₆H₅ radical and does not encompass -CH₂-C₆H₅. *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1579, 6 USPQ2d 1557, 1560 (Fed. Cir. 1988)(Without an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning.).

As the moving party, Watanabe bears the burden of proof. Having construed O'Brien's claims 1 and 2, Watanabe fails to sufficiently explain why one skilled in the art would find it obvious to modify Watanabe's proposed claims 33 and 36 and arrive at O'Brien claims 1 and 2. Specifically, Watanabe claims 33 and 36 differ from O'Brien in two respects - R¹ and R². On this record, Watanabe has failed to explain why one skilled in the art would modify the R²

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benzyloxymethyl moiety and arrive at a phenyloxy moiety while at the same time adding a R¹ halogen or C₁-C₆ alkyl group to Watanabe's unsubstituted aromatic compound.

Proposed Counts D and E

Contingent upon the denial of proposed counts A and C, Watanabe moves to substitute counts D and E for Counts 1 and 2. (Paper No. 36, p. 1). O'Brien opposes. (Paper No. 40).

Proposed count D is O'Brien claim 1 or Watanabe claim 34. Proposed count E is O'Brien claim 14 or Watanabe claim 35. (Paper No. 36, pages 5-6). Generally, Watanabe claim 34 is a species claim, i.e., directed to a single compound or pharmaceutical salt or hydrate thereof, and Watanabe claim 35 is a method of administering that compound.

Both Watanabe and O'Brien appear to agree that the Watanabe species of Watanabe claims 34 and 35 differs from O'Brien's claimed genus of claims 1 and 14 in one respect. Specifically, Watanabe species of claims 34 and 35 is an unsubstituted aromatic compound whereas O'Brien claims 1 and 14 requires a substituted aromatic compound with an R¹ being a C₁-C₆ alkyl or halogen, such as a chloro substituent. (Paper No. 36, p. 14 and Paper No. 40, p. 18).

Generalization should be avoided insofar as specific chemical structures are alleged to be prima facie obvious one from the other. *In re Grabiak*, 769 F.2d 729, 731, 226 USPQ 870, 872 (Fed. Cir. 1985). In order to prevent a hindsight-based obviousness analysis, the relevant inquiry for determining the scope and content of the prior art is whether there is a reason, suggestion, or motivation in the prior art or elsewhere that would have led one of ordinary skill in the art to

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combine the references. *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 665, 57 USPQ2d 1161, 1167 (Fed. Cir. 2000). Any motivation or suggestion to modify the prior art references must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995); *In re Gorman*, 933 F.2d 982, 986-87, 18 USPQ2d 1885, 1888, (Fed. Cir. 1991).

Watanabe argues that the addition of the methyl or halogen substituent to Watanabe's unsubstituted aromatic compound would have been obvious to one of ordinary skill in the art. Watanabe argues that the compound of Watanabe claim 34 has MMP inhibiting properties and would have motivated one skilled in the art to make homologs and analogs of the unsubstituted compound. (Paper No. 36, p. 14). For such a conclusion, Watanabe relies upon the testimony of Dr. Tatsuo Tsuru (WX 2069) and an article by John G. Topliss entitled "Utilization of Operational Schemes for Analog Synthesis in Drug Design" (WX 2070).

Dr. Tatsuo Tsuru testifies that the compound of Watanabe claim 34 and O'Brien claim 1 share a common base structural identity and share similar substituents on the active sites of the compound. (WX 2069, ¶ 111). According to Dr. Tsuru, one skilled in the art would have recognized that the compounds of Watanabe claim 34 and O'Brien claim 1 could have been made by similar methods. (WX 2069, ¶ 114). Knowing that the compound of Watanabe claim 34 was useful for the inhibition of MMP, Tsuru testifies that one skilled in the art would have been motivated to substitute a methyl or halogen group on the biphenyl group of the compound of Watanabe claim 34. (WX 2069, ¶ 116). Dr. Tsuru cites the article by Mr. Topliss as evidence

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of the motivation to conduct such a substitution. (WX 2069, ¶ 116).

The Topliss article teaches that:

A very common problem in drug design is to find the optimum substitution on a benzene ring or on the benzenoid portion of a fused ring system in an active lead compound for maximization of drug potency. Since there are many possible substituents and several different ring positions, the number of possible compounds to consider containing up to, say, two substituents is very large. Thus, it would be highly advantageous to determine at an early stage which of these compounds might really be worth synthesizing.

(WX 2070, p. 1). The Topliss article also teaches that the assumption in design is that the starting compound is the unsubstituted phenyl compound and that since many systems are $+\pi$ dependent, i.e., activity increases with increasing π values, "the p-chloro analog is a good first choice, particularly since the ease of synthesis, relative to other substituted phenyl compounds is favorable." (WX 2070, pages 2-4).

O'Brien argues that there is no motivation to modify Watanabe claims 34 and 35 and arrive at O'Brien's claimed invention. O'Brien cites the testimony of Mr. Picard and the Topliss article as evidence of the lack of motivation. (Paper No. 40, pages 20-21).

O'Brien directs our attention to the statement in Topliss that:

Also, some allowance will have to be made in any scheme used, for the degree of lipophilicity of the parent compound. In cases where log P for the parent compound is very high the $+\pi$ direction bias for the higher activity in the schemes would not be appropriate.

(WX 2070, p. 20). From this statement, O'Brien concludes that one skilled in the art would not add a substituent that increased the $+\pi$ value for a high π compound.

According to Mr. Picard, the calculated log P for Watanabe claims 34 and 35 is 3.18.

(OX 1002, ¶ 73). Mr. Picard testifies that 3.18 is a "high log P." (OX 1002, ¶ 74). As the

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methyl substituent has a log P of 0.6 and the chloro substituent has a log P of 0.7, Mr. Picard concludes that one skilled in the art would not substitute the methyl or chloro as they would further increase the log P of the Watanabe compound. (OX 1002, ¶ 75-80). Mr. Picard, however, does not state that 3.18 is "very high" such as that discussed by Topliss and also fails to sufficiently identify the basis for his opinion that 3.18 is "high."

Whether or not Watanabe claims 34 and 35 would render obvious O'Brien claims 1 and 14 is a difficult question. Yet, based on the evidence provided Watanabe has met its burden of proof. Specifically, I credit the testimony of Dr. Tsuru and the teachings of the Topliss article that one skilled in the art would substitute a chloro on the biphenyl group of Watanabe given Watanabe and O'Brien's close structural similarity, the similar active site substituents and that the p-chloro analog is known in the art as a good first choice for drug design since many systems are $+\pi$ dependent. In contrast, Mr. Picard's testimony fails to demonstrate that the compounds in question exhibit a "very high" $+\pi$ direction bias such one skilled in the art would not be led to form the p-chloro analog.

Watanabe has stated on record that Watanabe claim 34 and O'Brien claim 1 form the "same patentable invention" and that Watanabe claim 35 and O'Brien claim 14 form the "same patentable invention." On this record, Watanabe has demonstrated that Watanabe claims 34 and 35 would render obvious O'Brien claims 1 and 14. Further, Watanabe has met the procedural requirements of 37 C.F.R. 1.637 as well as the standards enunciated in *Louis v. Okada*, 59 USPQ2d 1073 (Bd. Pat. App. & Int. 2001). Accordingly, Watanabe Revised Preliminary Motion 3 is ***granted-in-part*** with Counts 1 and 2 substituted with proposed counts D and E. The claim

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correspondence is now changed with Watanabe claims 26-31 and 34 and O'Brien claims 1-13
corresponding to Count D and Watanabe claims 32 and 35 and O'Brien claims 14-18
corresponding to Count E.

Watanabe Revised Preliminary Motion 4

Watanabe Revised Preliminary Motion 4 requests entry of Watanabe claims 33-36. (Paper No. 37, p. 1). Watanabe's reply, however, recognizes that claims 33 and 36 would not correspond to Counts D and E should claims 33 and 36 be regarded as patenably distinct from O'Brien's claims. (Paper No. 44, pages 3-4). On the record presented, the parties have failed to sufficiently establish that O'Brien's claimed invention would render obvious Watanabe's proposed claims 33 and 36. Accordingly, Watanabe claims 33 and 36 are not entered. In contrast, Watanabe has demonstrated that proposed claims 34 and 35 represent the same patentable invention as that of O'Brien and that these claims correspond to new Counts D and E. As such, Watanabe Revised Preliminary Motion 4 is *granted-in-part* to allow entry of Watanabe claims 34 and 35.

Miscellaneous Matters

O'Brien has argued that the Board should not consider Watanabe's contingent request to enter proposed Counts D and E as Watanabe lacked proper authorization to file such a request. Specifically, O'Brien notes that Watanabe's original Preliminary Motion 3 requested entry of substitute counts A and B and that the December 23, 2002 Order permitted Watanabe to file a

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revised preliminary motion.

Watanabe Revised Preliminary Motion 3 is essentially two motions in one. First, the motion requests entry of substitute counts A and C. Included within the motion is a second requested motion, a contingent request for entry of substitute counts D and E. Watanabe did not seek permission to essentially file the second contingent motion. Nor was such permission contemplated or literally authorized in the December 23, 2002 Order. (Paper No. 33). Rather, the December 23, 2002 Order authorized Watanabe to file a single motion, specifically, "a Revised Watanabe Preliminary Motion 3" that was intended to address "why the subject matter added to the existing counts is material to the patentability of O'Brien's claims." (Paper No. 33).

The purpose of the expedited motions phase was to allow the parties to arrive at a just, speedy and inexpensive determination on the scope of the count. Watanabe's contingent request appears to serve that purpose. Further, O'Brien has failed to identify sufficient actual prejudice such that the contingent motion should not be considered at this time. Accordingly, Watanabe's contingent request was reviewed and considered on the merits.

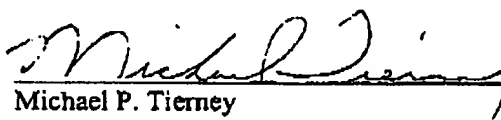
Watanabe argued that the requirements of the *Louis v. Okada* decision did not apply because Watanabe was not seeking to broaden the count based upon its earliest priority proofs. This argument is considered frivolous as Watanabe filed the motion to achieve senior status in this interference, i.e., be accorded its "best" priority benefit date. Watanabe, however, did comply with the standards set forth in the *Louis* decision and as such, no action need be taken.

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It is:

Ordered that Watanabe Revised Preliminary Motion 3 is *granted-in-part* with new Counts D and E substituted for Counts 1 and 2.

Further Ordered that Watanabe Revised Preliminary Motion 4 is *granted-in-part* with new claims 34 and 35 entered into Watanabe's involved 09/120,383 application.


Michael P. Tierney
Administrative Patent Judge

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